

**REMARKS**

By this reply, claim 1 has been amended. No new matter has been added by the amendment to claim 1. Claims 1-20 are pending in the application. Favorable consideration is respectfully requested in light of the following remarks.

**Telephonic Interview**

Applicants thank Examiner Sines for the courtesies extended to their undersigned representative during the telephonic interview conducted on April 25, 2006. Applicants separate record of the substance of the interview is incorporated in the following remarks.

**Information Disclosure Statement**

An Information Disclosure Statement is submitted herewith. The attached Form PTO-1449 cites a search report issued by the European Patent Office in a counterpart application, and the references JP 01112211 and EP 0 801 299 A1.

**Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-20 stand rejected under 35 U.S.C. § 112, second paragraph.

The Office Action asserts that it is unclear how the "control factors" are related to the data analysis and the preliminary production information and how it is utilized to obtain "control data." The Office Action further asserts that the recited "differentiation curve" constructed from the near infrared spectrum of a plurality of production products appears to be a "calibration curve."

These assertions were discussed during the interview. Regarding the "control factors," claim 1 recites comparing, when the absorbance spectrum includes wave length(s) at which the analysis deviation of the absorbance of the analysis sample is outside a tolerance limit determined based on the standard deviation, the wave length showing the analysis deviation of the absorbance outside the tolerance limit with production information given preliminarily in the data base in order to find out one or more control factors responsive to said analysis deviation of absorbance of the analysis sample, estimating control data for reclaiming the production process based on the one or more control factors, and controlling the production process so as to obtain production product within the said tolerance limit by inputting the control data to the production process step.

As was discussed during the interview, in the Amendment filed on December 7, 2005, Applicants referenced several Examples that are described in the specification, which show how the recited one or more "control factors" can be determined from data analysis and used to estimate "control data" for reclaiming a production process. For example, as discussed at page 11, last paragraph, of the December 7 Amendment, an excessive amount of raw material B was determined to be a "control factor" attributive to the occurrence of the abnormal analysis deviation. The control factor was used to determine "control data" (decreasing the supply of raw material B) to input to the production process step to reclaim the process. In other words, the "control factor" was determined to be a source or cause of the abnormal analysis deviation, and the "control data" was a response determined to address that source and reclaim the process. Other Examples of determining control factors and control data were also discussed in the December 7 Amendment.

Applicants submit that one having ordinary skill in the art would understand how the claimed "control factor" is related to the data analysis and the preliminary production information, and how the control factor is utilized to obtain the claimed "control data," in light of the original disclosure.

Regarding the "differentiation curve" and "calibration curve" recited in claim 1, this claim has been amended in the preamble to recite " a method for controlling production process without having resort to preparation of a calibration curve for predicting data for analysis samples" (emphasis added). As was discussed during the telephonic interview, in the Amendment filed on June 27, 2005, at page 18, last paragraph, Applicants explained that a calibration curve provides a predictive model for the value of a certain characteristic. In contrast, the claimed method compares observed data with actual data in a data base, not with data of a predictive model (corresponding to the conventional technique of comparison with a calibration equation).

The following remarks provide further explanation regarding differences between the recited "differentiation curve" and "calibration curve." In an ordinary absorptiometric analysis, an amount or concentration of objective material in a sample is determined using a preliminarily-prepared calibration curve. The calibration curve is a characteristic curve exhibiting a correlation between amounts or concentrations of objective material and absorbance spectra of specific wave length, which is prepared using preliminarily-analyzed samples. In a colorimetric analysis of a colored particles using visible light, colored particles, such as chlorophyll, absorb complimentary light having specific wave lengths and a calibration curve used in the analysis exhibits a linear correlation. Therefore,

absorbance spectra of specific wave lengths indicate an accurate value of amounts or concentrations of objective material. Thus, the calibration curve is easily prepared and used for quantitative analysis in cases where there is accurate correlation between amounts or concentrations of matter and absorbance of spectra.

In near-infrared absorptiometric analysis, absorbance of spectra relates to resonance between frequency of the infrared region and vibrational energy of molecules. Absorbance in the near-infrared is caused by over-tone and combination of standard frequency of the infrared region, which generates from the molecules, especially functional groups combined with hydrogen, such as O-H, N-H and C-H. The standard frequency of the infrared region and resonance of the near-infrared region vary with kinds, numbers and structures of the functional groups and other conditions.

In the near-infrared absorptiometric analysis, a correlation equation (calibration curve) is prepared by absorbance spectra in a wave length range exhibiting a correlation obtained by near-infrared absorptiometry and analytical results obtained by conventional analysis practice, in order to presume the prospective quantitative analysis value. A near-infrared absorptiometry accompanies an inherent defective characteristic feature that there reoccurs a shift of the spectrum due to influences by, for example, moisture content and temperature of the objective material. This spectrum shift may behave as if there is an alteration in the concentration of the component, or in another material property of the material to be observed, even if there is in fact no such alteration.

By near-infrared absorptiometry, a definite absorbance spectrum can be obtained steadily for a specific component under a definite observation condition and

with specific material properties, while the absorbance spectrum may be subject to deviation in the height or position of an absorbance peak due to alteration in the condition, such as concentration, particle size and temperature, or may vary due to interference with the absorption peaks for co-existing extraneous components. From a near-infrared absorbance spectrum, which includes information for a plurality of constituent components, a calibration curve (correlation equation) for each component is prepared by means of a statistical technique, on the basis of which analysis is attained.

For the preparation of the calibration curve, samples each having a definite composition and definite characteristic features are taken and subjected to conventional chemical analysis and to a near-infrared absorptiometric analysis. A correlation equation is derived by means of a statistical technique, such as a multiple linear regression analysis (MLR) or a partial least-squares method (PLS). A near-infrared absorbance spectrum includes a number of absorbance peaks, so that use of too many descriptive variables (assigned wave lengths) may result in reduction in the reliability due to over fitting of calibration curves. For this reason, there are used in general 2 to 5 descriptive variables for MLR and about 10 descriptive variables for PLS.

It is a common practice for detecting the component concentrations and material properties using a wave length range of the near-infrared region from 800 to 2,500 nm, that predicted values are estimated by selecting near-infrared spectral wave lengths each having a correlation with the results determined, using conventional analysis apparatus or conventional material property observing apparatus under preparation of a correlation equation to obtain a predicted value of

near-infrared analysis. However, the estimated predicted values represent only information derived using the calibration curve prepared from values for limited wave lengths in numbers of 2 to 5 or about 10 selected within the wide near-infrared region of from 800 nm to 2,500 nm.

Therefore, it is difficult using such a common practice to grasp the entire aspects or a delicate variation of a sample (or a product). Such practice is not effective, in particular, in the case where preparation of a calibration curve is not possible. Namely, it is difficult to prepare a calibration curve in the case that variation of the parameter to be detected, such as the concentration or material properties, is small, or that a temporal change of the sample occurs. These deficiencies of near-infrared absorptiometry using a calibration curve are due to the characteristic of the near-infrared resonance.

The claimed differentiation curve of a near-infrared spectrum chart is different from the above-described calibration curve. The calibration curve is prepared for predicting data for analysis samples using preliminarily analyzed samples in order to exhibit a correlation between amounts or concentrations of objective material and absorbance spectra of specific wave lengths. However, the differentiation curve is obtained by differentiation of a near-infrared spectrum chart obtained in the near-infrared absorptiometry, which exhibits no correlation between amounts or concentrations of objective material and absorbance spectra of specific wave lengths.

The baseline of a near-infrared spectrum chart tends to rise up on the side of longer wave lengths due to influences by moisture content and the like and exhibits overlaps of spectral peaks. In Figure 2 of the present application, the original near-

infrared absorption spectrum curve (A) extending from the left bottom side to the right top side of the figure shows a baseline shifting on the side of longer wave lengths and overlapped peaks. Accordingly, the detection of the peaks and the calculations of the standard average intensity and of the standard deviations from the original absorption spectrum curve (A) are difficult.

The differentiation-treated spectrum obtained by differentiation of the original absorption spectrum curve has a flat horizontal baseline and the over lapped peaks become separated because the differentiation-treated curve shows variation rates of the original curve. However, the phase of the peaks is changed. Accordingly, the calculations of the standard average intensity and of the standard deviations from the original absorption spectrum curve (A) are difficult.

In contrast, the second order differentiation-treated spectrum has a flat horizontal baseline and the peaks are inverted with sharpened reproduction of lower peaks and the over lapped peaks become separated. The curve (B) of Figure 2, representing a second derivative curve in which the original spectral chart is twice differentiated, exhibits a flattened horizontal baseline and isolated-appearing, emphasized absorption peaks, which have an inverted shape of the peaks of the curve (B) in the same phase. Accordingly, the detection of the peaks and the calculations of the standard average intensity and of the standard deviations from the second order differentiation-treated absorption spectrum curve (A) are easy. See the description of Figure 2 at page 25 of the specification.

Therefore, the differentiation-treated spectrum of the claimed method is obtained by differentiation of the original absorption spectrum curve and is different from the recited calibration curve, which is prepared for predicting data for analysis

samples using preliminarily analyzed samples in order to exhibit a correlation between amounts or concentrations of objective material and absorbance spectra of specific wave length.

The claimed data base is different from the claimed calibration curve. The data base is constructed from a differentiation curve of a near-infrared spectrum chart obtained using a plurality of production products that had been judged by conventional chemical analysis to be rated products, by calculating standard deviations and the average intensity of the standard samples (standard average intensity) in respect of each of the wave lengths selected from the spectrum included in the the analysis range at a constant interval.

The data base carries information of standard deviations and the average intensity for discriminating as to whether or not the products are a rated product. The discrimination is effected as to whether the analysis deviation is within a tolerance limit determined based on the standard deviation stored in the data base, or not. The case of being within the tolerance limit is judged as "rated" and the case of being outside of the tolerance limit is judged as "extra-rated." Therefore, the data base of the claimed method is different from a calibration curve exhibiting a correlation between amounts or concentrations of objective material and absorbance spectra of specific wave lengths.

In near-infrared absorptiometric analysis using a calibration curve, the assigned wave lengths used in the detection are the same as the assigned wave lengths used as descriptive variables in the calibration. As discussed above, there are used in general 2 to 5 assigned wave lengths as the descriptive variables for MLR and about ten assigned wave lengths as the descriptive variables for PLS for



preparing calibration curves. These assigned wave lengths are the specific ones for the detection and determination of the objective materials.

The selected wave lengths of the claimed method are different from the assigned wave lengths in the near-infrared absorptiometric analysis using a calibration curve. The selected wave lengths are selected from the spectrum included in the analysis range at a constant interval regardless of the detection and determination of the objective materials.

In the claimed method, the discrimination of whether a rated product or not is effected as to the selected wave lengths whether the analysis deviation is within a tolerance limit determined based on the standard deviation, or not. Therefore, the selected wave lengths are different from the assigned wave lengths.

As discussed above, the claimed method for controlling production process does not need preparation and utilization of a calibration curve for predicting data for analysis samples.

Applicants submit that one having ordinary skill in the art would also understand the meaning of the claimed differentiation curve and calibration curve in light of the original disclosure. Thus, it is submitted that claims 1-20 are in compliance with the provisions of 35 U.S.C. § 112, second paragraph. Therefore, withdrawal of the rejection is respectfully requested.

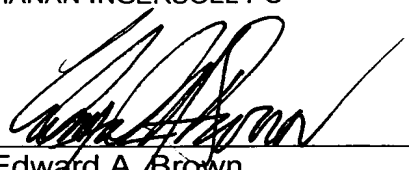
**Conclusion**

For the foregoing reasons, allowance of the application is respectfully requested. If there are any questions concerning this response, the Examiner is respectfully requested to contact the undersigned at the number given below.

Respectfully submitted,

BUCHANAN INGERSOLL PC

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